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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

16

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,024

Applicant(s)

BISARO, DAVID

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9, 12, 13, 17, 18, 20, 23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-9, 12, 13, 17, 18, 20, 23, and 25-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated July 28, 2003, paper number 16.
2. Applicant has cancelled claims 1-6, 10, 11, 14-16, 19, 21, 22 and 24, and amended claims 7-9, 12, 13, 17, 18, 20 and 23. New claims 25-28 have been added. Claims 7-9, 12, 13, 17, 18, 20, 23, and 25-28 are pending, and are examined in the instant action.
3. Applicant should note that claim 24 has been cancelled and that new claims 24-27 are added. New claims must be ordered sequentially; therefore the new claims have been renumbered to claims 25-28, by Rule 126 amendment.
4. This action is made FINAL necessitated by Applicant's amendment.
5. All rejections not addressed below have been withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-second

7. Claims 7-9, 12, 13, 17, 18, 20, 23, and 25-28 are rejected under 35 U.S.C. 112-2nd. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Applicant has amended claim 7 to recite:

A recombinant polynucleotide encoding a mutant Begomovirus transcription activator protein wherein said recombinant polynucleotide is a modified open reading frame of a selected wild-type AL2 gene from a Begomovirus strain, and wherein said mutant Begomovirus transcription activator protein is a mutant form of a corresponding wild-type Begomovirus transcription activator protein expressed by the selected wild-type AL2 gene; said recombinant polynucleotide comprising a first mutation in the open reading frame which encodes amino acid 83 to amino acid 129 of the wild-type transcription activator protein and a second mutation of the open reading frame which encodes amino acid 23 to amino acid 43 of the wild-type transcription activator protein, wherein each of said first and second mutations comprises addition to, deletion of, or replacement of one of more amino acid, or a combination thereof.

Claim 7 is unclear because

- “modified”(line 3) is unclear because “modified” refers to “a first mutation” (line 7) and a second mutation (line 9), “wherein each of said first and second mutations comprises addition to, deletion of, or replacement of one of more amino acid, or a combination thereof ” (line 11-12). The metes and bounds of these terms are not clear. This language reads on an infinite number of polypeptides/polynucleotides.
- The frame of reference for the amino acid numbers 83 and 129, 23 and 43, is not given. Without a standard these numbers are meaningless. All subsequent recitations of this language are also rejected.

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Applicant traverses, stating primarily that Figure 1 shows the amino acid sequence for several transcription activator protein isolated from different Begomovirus. As stated in the "brief description of the figures," the sequences are all aligned, oriented in the customary fashion starting with amino acid 1 at the N-terminal end (located on the top left of the page, and ending with amino acid number 131 (located at the C-terminal on the lower right side).

Applicant's traversal has been considered and is unpersuasive because there are no numbers assigned to any amino acid in this figure, there is no stated relationship of the first panel of sequences or the second or the third panels of sequence. Furthermore, these sequences have gaps in them, which make it impossible to extrapolate within any given panel.

- "Gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All subsequent recitations of this language are also rejected.

In claim 13,

- what is "the central region"?

Applicant traverses, stating primarily (Response, p. 6) saying that "central region" has been changed to "central domain".

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Applicant's traversal has been considered and is unpersuasive this language has not been amended in the claim. Furthermore, the amended language has the same problem as that of the original language. What amino acids and structural motifs designate this region?

In claims 25,

- what does "an acidic domain at amino" (line 2) mean?
- What is "a cysteine-histidine domain" ?
-

In claim 26,

- what does "an acidic domain at amino" (line 2) mean?
- What is "a cysteine-histidine domain" ?
- What is the "acidic domain" (line 5)?

In claim 28,

- What is "a cysteine-histidine domain" ?
- What is the "acidic domain" ?

Claim Rejections - 35 USC § 112, first paragraph

Written description

8. Claims 7-9, 12, 13, 17, 18, 20, 23, and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Claim 7 is drawn to:

A recombinant polynucleotide encoding a mutant Begomovirus transcription activator protein wherein said recombinant polynucleotide is a modified open reading frame of a selected wild-type AL2 gene from a Begomovirus strain, and wherein said mutant Begomovirus transcription activator protein is a mutant form of a corresponding wild-type Begomovirus transcription activator protein expressed by the selected wild-type AL2 gene; said recombinant polynucleotide comprising a first mutation in the open reading frame which encodes amino acid 83 to amino acid 129 of the wild-type transcription activator protein and a second mutation of the open reading frame which encodes amino acid 23 to amino acid 43 of the wild-type transcription activator protein, wherein each of said first and second mutations comprises addition to, deletion of, or replacement of one or more amino acid, or a combination thereof.

There is no structural description of what comprises the modified transcription activator protein. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Applicant traverses, stating primarily that Applicant has provided information about discrete domains and corresponding amino acid sequence positions in WO 99/630,054.

Applicant's traversal has been considered and is unpersuasive because the specification must be complete as of the date of filing, and the relationship of the designed WO document to the instant case is unknown. Nor is the WO document of record in this case.

Applicant traverses, stating primarily that Applicant has disclosed the structural properties of the transcription activator protein, including its molecular weight, 15 kDa. That substitutions insertions and deletions are to a made in the contest of specific codons. That since insertions and deletions are based upon discrete amino acids, the size of the polynucleotide mutants and resulting proteins could readily be calculated by one of ordinary skill.

Applicant's traversal has been considered and is unpersuasive because claim 7 recites "wherein each of said first and second mutations comprises addition to, deletion of, or replacement of one of more amino acid, or a combination thereof". This language describes an infinite number of additions, deletions, or replacements of one of more amino acid, or a combinations, with no size of the product defined, and without any recitation of function. Neither the size of the gene nor that of the corresponding protein is able to defined, because of the infinite number of possibilities.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application

was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

Claim Rejections - 35 USC § 112-Enablement

9. Claims 7-9, 12, 13, 17, 18, 20, 23, and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Applicant traverses, stating primarily (Response, p.9) that, as recited in claim 7, the isolated recombinant AL2 polynucleotide comprises mutations in two specific regions of an AL2 gene sequence. That the claims does not recite "any mutation" in "any" region.

Applicant's traversal has been considered and is unpersuasive because claim 7 recites "wherein each of said first and second mutations comprises addition to, deletion of, or replacement of one of more amino acid, or a combination thereof". This language describes an infinite number of additions, deletions, or replacements of one of more amino acid, or a combinations, with no size of the product defined, and without

any recitation of structure or function. Neither the size of the gene nor that of the corresponding protein able to defined, because of the infinite number of possibilities.

Remarks

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

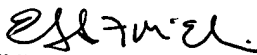
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD

Patent Examiner

Art Group 1638

October 17, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600